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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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**Food and Drug Administration**

**21 CFR Parts 524 and 556**

## Ophthalmic and Topical Dosage Form New Animal Drugs; Eprinomectin

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA provides for topical use of eprinomectin on cattle for treatment and control of two additional gastrointestinal roundworms and to establish of an acceptable daily intake (ADI) and tolerance for eprinomecrin residues in cattle muscle.

**EFFECTIVE DATE:** (*Insert date of publication in the* **Federal Register**.)

**FOR FURTHER INFORMATION CONTACT:** Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

**SUPPLEMENTARY INFORMATION:** Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077, is sponsor of NADA 141–079 that provides for use of Ivomec® Eprinex™ Pour-On (5 milligrams per milliliter eprinomectin) on beef and dairy cattle for treatment and control of gastrointestinal roundworm, lungworm, cattle grub, lice, mange mite, and horn fly infections. The sponsor filed a supplemental NADA that provides for use of the product for treatment and control of *Strongyloides papillosus* (adults) and *Trichostrongylus longispicularis* (adults). The supplemental NADA is approved as of August 9, 1998, and 21 CFR 524.814(d)(2) is revised to reflect the approval. The basis of approval is discussed in the freedom of information summary.

A tolerance for residues of eprinomectin in the muscle of cattle has not previously been established. At this time, 21 CFR 556.227 is amended to establish a tolerance for eprinomectin residues in cattle muscle. Also, the regulation is amended to establish an ADI for safe daily human intake of residues of eprinomectin. The ADI is the amount of total drug residue that can be safely consumed by humans every day.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under 21 U.S.C. 360b(c)(2)(F)(iii), this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning August 9, 1998, because the supplement contains substantial evidence of the effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use of the drug as approved in this supplemental NADA.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**List of Subjects**

*21 CFR Part 524*

Animal drugs.

*21 CFR Part 556*

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 524 and 556 are amended as follows:

## PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

2. Section 524.814 is amended by revising paragraph (d)(2) to read as follows:

### § 524.814 Eprinomectin.

* * * * *

(d) * * *

(2) *Indications for use.* The drug is used in beef and dairy cattle for treatment and control of gastrointestinal roundworms (*Haemonchus placei* (adult and L4), *Ostertagia ostertagi* (adult and L4, including inhibited L4), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult and L4), *T. longispicularis* (adult), *Cooperia oncophora* (adult and L4), *C. punctata* (adult and L4), *C. surnabada* (adult and L4), *Nematodirus helvetianus* (adult and L4), *Bunostomum phlebotomum* (adult and L4), *Oesophagostomum radiatum* (adult and L4), *Strongyloides papillosus* (adults), *Trichuris* spp. (adults)); lungworms (*Dictyocaulus viviparus*, adult and L4); cattle grubs (all parasitic stages *Hypoderma lineatum*, *H. bovis*); lice (*Damalinia bovis*, *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mange mites (*Chorioptes bovis*, *Sarcoptes scabiei*); and horn flies (*Haematobia irritans*). Controls and protects from reinfection of *D. vivaparus* for 21 days after treatment and *H. irritans* for 7 days after treatment.

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## PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

**Authority:** 21 U.S.C. 342, 360b, 371.

4. Section 556.227 is revised to read as follows:

**§ 556.227 Eprinomectin.**

(a) *Acceptable daily intake (ADI).* The ADI for total residues of eprinomectin is 10 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*. Tolerances are established for residues of eprinomectin B1a (marker residue) in milk of 12 parts per billion, in liver (target tissue) of 4.8 parts per million, and in muscle of 100 parts per billion.

(2) [Reserved]

Dated: Sept 20 1998

September 20, 1998

Margaret Ann Miller

Margaret Ann Miller
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

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